

COVID-19 Vaccine Safety Technical (VaST) Work Group

VaST assessment

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COVID-19 Vaccine Safety Technical (VaST) Work Group

Objectives

- Review, evaluate, and interpret post-authorization/approval COVID-19 vaccination safety data
- Serve as the central hub for technical subject matter expertise from federal agencies conducting post-authorization/approval safety monitoring
- Advise on analyses, interpretation, and presentation of vaccine safety data
- Provide updates to the ACIP COVID-19 Vaccines Work Group and the entire ACIP on COVID-19 vaccine safety

COVID-19 Vaccine Safety Technical (VaST) Work Group

Activities

- From December 21, 2020 through February 24, 2023
 - 71 independent meetings to review vaccine safety data
 - 17 joint meetings with ACIP COVID-19 Vaccines Work Group
 - 22 ACIP meeting presentations or reports with VaST assessments

VaST assessment

- Statistical signal for ischemic stroke in the Vaccine Safety Datalink following bivalent COVID-19 booster vaccination
- Myocarditis/pericarditis following mRNA COVID-19 vaccination

VaST assessment – statistical signal for ischemic stroke/TIA in the Vaccine Safety Datalink (VSD)

- The statistical signal among persons aged ≥ 65 years for ischemic stroke/transient ischemic attack (TIA) following bivalent Pfizer-BioNTech COVID-19 booster vaccination in VSD is based on limited data and has been attenuating over time.
- A signal has not been observed in two other U.S. active vaccine safety monitoring systems¹, nor in data from other countries².
 - The U.S. systems differ from each other; the VSD and VA analyses included TIA with ischemic stroke, while FDA CMS analysis did not.
 - VSD is the only U.S. system that uses concurrent comparator groups.
 - The VA and FDA CMS analyses have not evaluated simultaneous administration with influenza vaccination.

¹FDA analysis of Centers for Medicare and Medicaid Services (CMS) data, and Department of Veterans Affairs (VA) rapid cycle analyses

²Israel and European countries

VaST assessment – statistical signal for ischemic stroke/TIA in the Vaccine Safety Datalink (VSD)

- No increased rate ratio for ischemic stroke/TIA following bivalent Moderna COVID-19 booster vaccination.
- Previous surveillance in VSD and other U.S. systems found no evidence of increased risk of ischemic stroke/TIA after the primary series or monovalent COVID-19 booster vaccination for either Pfizer-BioNTech or Moderna products.

VaST assessment – statistical signal for ischemic stroke/TIA in the Vaccine Safety Datalink (VSD)

- The cause of the increased rate ratio is unclear; potential contributing factors include simultaneous administration of bivalent COVID-19 booster and influenza vaccines* or unmeasured confounding or bias.
- VaST would like to review additional data on simultaneous administration of bivalent COVID-19 booster and influenza vaccination.
- VaST highlighted several areas for further exploration:
 - Assess the impact of recent respiratory viral illness (e.g., COVID-19, influenza) on risk of ischemic stroke/TIA.
 - Analyses in VSD highlighted potential reasons for the lower rate of ischemic stroke/TIA in the vaccinated comparator group, which could be contributing to the increased rate ratio. These should be explored further.

*Most VSD participants aged ≥ 65 years received high-dose influenza vaccine in 2022-23 season

VaST assessment – myocarditis/pericarditis following mRNA COVID-19 vaccination

- VaST has reviewed data on myocarditis/pericarditis following COVID-19 vaccination since April 2021 and provided several assessments at ACIP meetings.
 - Rates after the monovalent primary series, monovalent booster doses and bivalent booster doses have been assessed.
 - Rates highest in adolescent and young adult males following primary series dose 2 and first monovalent booster dose.
 - Outcomes after the monovalent primary series and monovalent booster doses have also been assessed.
- Data on rates after bivalent COVID-19 booster vaccination are limited.
 - Current data in VSD do not raise additional concerns about myocarditis following bivalent COVID-19 booster vaccination.

VaST – future plans

- The ACIP COVID-19 Vaccines Work Group will continue to review safety data
- VaST is preparing to transition review of vaccine safety data to the ACIP COVID-19 Vaccines Work Group

VaST Members

VaST Members

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